Bayer HealthCare
Biological Products Division

February 24, 2005

Charlotte M Williams
Department Of Health & Human Services
Dockets Management Branch
5630 Fishers Lane
Rockville, MD 20857

Carol M. Moore
Vice President
Worldwide Regulatory Affairs
Responsible Head / Agent

RE: Docket No: 2005N-0010 - Notice of Proposed withdrawal of NDAs

Dear Ms. Williams:

Attached is a copy of a notice received at the Bayer HealthCare Biological Products plant in Berkeley, California.

Upon reading the notice, it has been determined that the drug application is not for a product produced at our Berkeley site. The original notice will be forwarded to Joseph Scheeren, Senior Vice President, Bayer HealthCare LLC Pharmaceutical Division, Global Regulatory Affairs, 400 Morgan Lane West Haven, CT 06516-4175.

Bayer HealthCare LLC
Biological Products Division
800 Dwight Way, P.O. Box 1986
Berkeley, CA 94701-1986

Phone: 510-705-5224
Fax: 510-705-4712
carol.moore.b.@bayer.comBayer

Sincerely,

Carol M Moore
Vice President
Worldwide Regulatory Affairs
Responsible Head/Agent

CM:ar

cc: Joseph Scheeren

enclosure

2005N-0010 LET 2

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

Fedruary 3, 2005

Docket Nos. 2005N-0010

Dear Sir or Madam:

Enclosed is a notice that published in the Federal Register on January 28, 2005 announcing the proposed to withdraw approval of thirteen new drug applications.

In reply, please refer to the docket number above.

Sincerely,

Charlotte Williams

Charlotte Williams
Dockets Management Branch

Enclosure

CAI- Green tag was missing upon receipt from mail room. MZ

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Display Date 1/27/05
Publication Date 1/28/05
Docket R. LEDESMA

DDM

[Docket No. 2005N–0010]

High Chemical Co. et al.; Proposal to Withdraw Approval of 13 New Drug Applications; Opportunity for a Hearing

70 FR 4134
1-28-05

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

hearing request due 2-28-05
data supporting request 3-29-05

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for a hearing on the agency's proposal to withdraw approval of 13 new drug applications (NDAs) from multiple sponsors. The basis for the proposal is that the sponsors have repeatedly failed to file required annual reports for these applications.

DATES: Submit written requests for a hearing by [*insert date 30 days after date of publication in the* **Federal Register**]; submit data and information in support of the hearing request by [*insert date 60 days after date of publication in the* **Federal Register**].

ADDRESSES: Requests for a hearing, supporting data, and other comments are to be identified with Docket No. 2005N–0010 and submitted to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Florine P. Purdie, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

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2005N-0010

SUPPLEMENTARY INFORMATION: The holders of approved applications to market new drugs for human use are required to submit annual reports to FDA concerning each of their approved applications in accordance with § 314.81 (21 CFR 314.81). The holders of the approved applications listed in the following table have failed to submit the required annual reports and have not responded to the agency's request by certified mail for submission of the reports.

Application No.	Drug	Applicant
NDA 0–763	Sterile Solution Procaine Injection 2% (Procaine Hydrochloride (HCl))	High Chemical Co., 1760 N. Howard St., Philadelphia, PA 19122
NDA 2–959	Nicotinic Acid (Niacin) Tablets	The Blue Line Chemical Co., 302 South Broadway, St. Louis, MO 63102
NDA 4–236	Sherman (thiamine HCl) Elixir	Do.
NDA 4–368	Ascorbic Acid Tablets	Do.
NDA 5–159	D.S.D. (diethylstilbestrol dipropionate)	Do.
NDA 9–452	Multifuge (piperazine citrate) Syrup	Do.
NDA 10–055	Fire Gard Three-Alarm Burn Relief (Methylcellulose)	Gard Products, Inc., 2560 Tara Lane, Brunswick, GA 31520
NDA 10–337	Fling Antiperspirant Foot Powder	Bauer & Black, A Division of The Kendall Co., One Federal St., Boston, MA 02110
NDA 10–541	BY–NA–MID (Butylphenamide or B and Zinc Oxide or Stearate) Tincture, Ointment, Lotion, and Powder	Miles Inc., Cutter Biological, P.O. Box 1986, Berkeley, CA 94701
NDA 10–823	BIKE Foot and Body Powder	Bauer & Black, A Division of The Kendall Co.
NDA 10–824	BIKE Anti-Fungal Aerosol Spray	Do.
NDA 11–233	TKO with Entrin Roll-On Liquid	Modern-Labs, Inc., Maple Rd., Gambrills, MD 21504
NDA 19–432	Spectamine (Iofetamine Hydrochloride I–123) Injection	IMP Inc., 8050 El Rio, Houston, TX 77054

Therefore, notice is given to the holders of the approved applications listed in the table and to all other interested persons that the Director of the Center for Drug Evaluation and Research proposes to issue an order under section 505(e) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(e)) withdrawing approval of the applications and all amendments and supplements thereto on the ground that the applicants have failed to submit reports required under § 314.81.

In accordance with section 505 of the act and 21 CFR part 314, the applicants are hereby provided an opportunity for a hearing to show why the applications listed previously should not be withdrawn and an opportunity to raise, for administrative determination, all issues relating to the legal status of the drug products covered by these applications.

An applicant who decides to seek a hearing shall file: (1) A written notice of participation and request for a hearing (see **DATES**) and (2) the data, information, and analyses relied on to demonstrate that there is a genuine and substantial issue of fact that requires a hearing (see **DATES**). Any other interested person may also submit comments on this document. The procedures and requirements governing this notice of opportunity for a hearing, notice of participation and request for a hearing, information and analyses to justify a hearing, other comments, and a grant or denial of a hearing are contained in § 314.200 and 21 CFR part 12.

The failure of an applicant to file a timely written notice of participation and request for a hearing, as required by § 314.200, constitutes an election by that applicant not to avail itself of the opportunity for a hearing concerning the proposal to withdraw approval of the applications and constitutes a waiver of any contentions concerning the legal status of the drug products. FDA will then withdraw approval of the applications and the drug products may not thereafter lawfully be marketed, and FDA will begin appropriate regulatory action to remove the products from the market. Any new drug product marketed without an approved NDA is subject to regulatory action at any time.

A request for a hearing may not rest upon mere allegations or denials, but must present specific facts showing that there is a genuine and substantial issue of fact that requires a hearing. Reports submitted to remedy the

deficiencies must be complete in all respects in accordance with § 314.81. If the submission is not complete or if a request for a hearing is not made in the required format or with the required reports, the Commissioner of Food and Drugs (the Commissioner) will enter summary judgment against the person who requests the hearing, making findings and conclusions, and denying a hearing.

All submissions under this notice of opportunity for a hearing must be filed in four copies. Except for data and information prohibited from public disclosure under section 301 of the act (21 U.S.C. 331(j)) or 18 U.S.C. 1905, the submissions may be seen in the Division of Dockets Management (see **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the act (section 505 (21 U.S.C. 355)) and under authority delegated to the Director, Center for Drug Evaluation and Research, by the Commissioner.

Dated: 1/19/05
January 19. 2005.

Jeffrey Shuren,
Assistant Commissioner for Policy.

[FR Doc. 05–????? Filed ??–??–05; 8:45 am]

BILLING CODE 4160–01–S